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10/591,570

04/26/2007

Frans Witteveen

207,802

6231

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EXAMINER

SHOMER, ISAAC

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/591,570 | Applicant(s) WITTEVEEN ET AL. | |
| | Examiner ISAAC SHOMER | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 22 December 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21-25 and 27-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skelbaek et al. (WO 91/17821).

Skelbaek et al. (hereafter referred to as Skelbaek) teaches, inter alia, microparticles comprising fish gelatine, saccharose (sucrose)¹, lovage oil, and starch (a polysaccharide) wherein said microparticles are spray dried, as of Skelbaek, page 17, Example 9. The product fraction of said microparticles is sized between 100-500 microns, as of Skelbaek, page 17 lines 27-28. In a separate embodiment, hydrogenated castor oil (i.e. glyceryl tri-12-hydroxystearate),² as well as stearin as of Skelbaek, page

¹ Saccharose and sucrose are the same compound, as of CAS Registry Record 57-50-1.

² That hydrogenated castor oil is glyceryl tri-12-hydroxystearate is taught by Greenstein (US Patent 4,032,350), column 7 lines 7-8.

Art Unit: 1612

5 line 5, is suggested for inclusion in a concentration of 2-10%, as of Skelbaek, page 5 lines 18-19, wherein the melting point of glyceryl-12-hydroxystearate appears to exceed 60 C.³ Ethyl cellulose is suggested to be included in a ratio of up to 30%, as of Skelbaek, page 5 lines 15-16. Lovage oil is a flavorant, as of Skelbaek, page 4 line 9, and the gelatine is suggested to be a matrix former, and to have a bloom strength from 0 to 300, as of Skelbaek, page 4 lines 23-24. Uses in toothpaste (page 1 line 12) and chewing gum (page 1 line 27) are suggested by Skelbaek. The taught amount of gelatine in Skelbaek, Example 9 appears to be (330 g gelatine / (330 g gelatine + 330 g sucrose + 50 g flavorant)), as of Skelbaek, page 17 lines 5-9 or about 46% gelatine. Skelbaek appears to provide delayed flavor release; this property was provided by the prior art cited by Skelbaek (as of Skelbaek, page 2 lines 1-4) and appears to be solved by the invention of Skelbaek itself, as of Skelbaek, page 2 lines 11-15. Incorporation in an amount of about 1-2% in chewing gum is taught as of Skelbaek, page 15 lines 6-8. Said composition appears to comprise 98% of product particles in one embodiment, as of Skelbaek, page 8 lines 17-19.

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such “picking and choosing” within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables

³ Melting points of 65-90 degrees C are taught by the CAS Registry Record for CAS 139-44-6.

Art Unit: 1612

specifically hydrogenated castor oil, ethylcellulose and sucrose, anticipation cannot be found.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007) (quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients specifically hydrogenated castor oil, ethylcellulose and sucrose, from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

The gelatine bloom strength and the concentrations of gelatine, fat, flavoring, and carbohydrates overlaps with the instantly claimed concentrations as recited in claim 21.

Art Unit: 1612

While the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness.

In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skelbaek et al. (WO 91/17821) as applied to claims 21-25 and 27-37 above, and further in view of Venema et al. (EP 0839516 A1)..

Skelbaek teaches a composition comprising particles flavoring, gelatine, triglycerides, ethylcellulose and sucrose for the purpose of controlled release of flavor in toothpaste or chewing gum.

Skelbaek does not teach a eucalyptus flavoring, as of claim 26.

Venema et al. (hereafter referred to as Venema) teaches a dentifrice composition preferably in the form of a toothpaste, as of Venema, abstract. Venema suggests flavorants and sweeteners, as of Venema, page 3 lines 22-26. Said flavorants include eucalyptus, as of Venema, page 3 line 23, and the combination of flavorants and sweeteners are suggested to be between 0.1% and 10%. Particles are sized between 500-800 microns, as of Skelbaek, page 3 line 27.

It would have been *prima facie* obvious for one of ordinary skill in the art to have substituted eucalyptus flavoring for the flavoring in Skelbaek. This is because eucalyptus is known to be suitable for the intended use of providing a flavor in dentifrice compositions. As such, one of ordinary skill in the art would have been motivated to have predictably substituted eucalyptus flavoring for that of Skelbaek with a reasonable

Art Unit: 1612

expectation of successfully providing flavor to the composition of Skelbaek. The simple substitution of one known element for another to obtain predictable results is prima facie obvious. See MPEP 2143, Exemplary Rationale B.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/591,570
Art Unit: 1612

Page 7

/I. S./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612